

**IN THE SUPERIOR COURT OF THE STATE OF DELAWARE**

SOFREGEN MEDICAL INC., a Delaware Corporation; and SOFREGEN MEDICAL IRELAND LIMITED, an Irish Private Limited Company,

Plaintiffs/Counterclaim-Defendants,

v.

ALLERGAN SALES, LLC, a Delaware Limited Liability Company; and ALLERGAN PHARMACEUTICALS HOLDINGS (IRELAND), an Irish Incorporated Private Unlimited Liability Company,

Defendants/Counterclaim-Plaintiffs.

C.A. No.: N20C-03-319 EMD CCLD

*Upon Defendant/Counterclaim-Plaintiffs' Motion to Exclude Dr. Kaufman's Expert Reports and Testimony*

**DENIED**

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**DAVIS, J.**

**I. INTRODUCTION**

This is a breach of contract and fraudulent inducement action assigned to the Complex Commercial Litigation Division of this Court. In November 2016, Plaintiffs Sofregen Medical Inc. and Sofregen Medical Ireland Limited (collectively, "Sofregen") purchased from Allergan

Sales, LLC and Allergan Pharmaceuticals Holdings (Ireland) (collectively, “Allergan”) certain “silk biomaterial surgical mesh” (“SERI”) products for use in reconstructive surgeries.<sup>1</sup> The purchase occurred via an asset purchase agreement (the “APA”) between Sofregen and Allergan.<sup>2</sup>

## **II. THE MOTION IN LIMINE**

Allergan seeks to exclude the expert reports and testimony of Dr. Jedediah Kaufman. Dr. Kaufman is a practicing general surgeon “that evaluates clinical trial data to determine which medical devices to employ in his practice.”<sup>3</sup> Dr. Kaufman also reviews safety profiles and costs of medical devices in advising hospitals on which products should be purchased and used.<sup>4</sup> Sofregen retained Dr. Kaufman as an expert witness to opine on the materiality of the SURE-002 study, SURE-006 study, among other relevant studies.<sup>5</sup> It appears Dr. Kaufman’s expert opinions touch on how a prospective purchaser (a clinician) of SERI would view the product, as well as the reasonableness of Sofregen’s reliance on Allergan’s pre-closing representations regarding SERI.<sup>6</sup> These issues were front and center in the Court’s Summary Judgment Opinion, and the Court cited Dr. Kaufman’s expert reports multiple times in that opinion.<sup>7</sup>

Allergan makes four arguments to exclude Dr. Kaufman’s expert reports and testimony: (i) Dr. Kaufman misunderstands the nature of expert opinions; (ii) Dr. Kaufman is not qualified because he lacks the requisite knowledge, skill, experience, training, or education; (iii) several of Dr. Kaufman’s opinions should be excluded because they are not supported by sufficient facts or

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<sup>1</sup> Second Amended Complaint (“Second Am. Compl.”) ¶ 1. D.I. No. 20.

<sup>2</sup> *Id.*

<sup>3</sup> D.I. 186 at 2.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.* at 3-4.

<sup>6</sup> *Id.* at 4.

<sup>7</sup> *See* D.I. 182 at 4, 7, 18.

data; and (iv) Dr. Kaufman's "non-expert opinions" should be excluded because they are inadmissible "common sense opinions."<sup>8</sup>

Sofregen responds with five points: (i) Dr. Kaufman is a qualified expert because he is a surgeon opining on the significance of clinical trial data authored by medical doctors about a surgical mesh used by surgeons; (ii) Dr. Kaufman is not offering opinions on topics outside his scope of expertise, such as FDA and regulatory guidelines and procedures; (iii) Dr. Kaufman's opinions are supported by sufficient facts and data; (iv) Dr. Kaufman is not providing any "non-expert opinions"; and (v) Dr. Kaufman's opinions will assist the trier of fact, *i.e.*, the Court.<sup>9</sup> Sofregen contends that most of Allergan's arguments go to credibility, not admissibility.<sup>10</sup>

The Court agrees with Sofregen's arguments and will **DENY** Allergan's motion to exclude Dr. Kaufman.

### III. LEGAL STANDARD

Delaware Rule of Evidence 702 governs the admission of expert testimony:

A witness who is qualified as an expert by knowledge, skill experience, training, or education may testify in the form of an opinion or otherwise, if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based upon sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the witness has applied the principles and methods reliably to the facts of the case.<sup>11</sup>

D.R.E. 702 is substantially similar to F.R.E. 702.<sup>12</sup> F.R.E. 702 was interpreted and further explained in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,<sup>13</sup> and *Kumho Tire Co., Ltd. v.*

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<sup>8</sup> See D.I. 181 at 3-10.

<sup>9</sup> See D.I. 186 at 4-11.

<sup>10</sup> *Id.* at 7-8.

<sup>11</sup> D.R.E. 702.

<sup>12</sup> *Bowen v. E.I. DuPont de Nemours & Co., Inc.*, 906 A.2d 787, 794 (Del. 2006).

<sup>13</sup> 509 U.S. 579 (1993).

*Carmichael*.<sup>14</sup> Delaware courts have adopted the holdings in *Daubert* and *Carmichael*.<sup>15</sup> A trial judge must ensure an expert's testimony is both relevant and reliable when its admission is challenged.<sup>16</sup> Delaware requires the gatekeeping judge to engage in a five-step analysis to determine the admissibility of proffered expert testimony.<sup>17</sup> The Court must ensure that:

(1) the witness is qualified as an expert by knowledge, skill, experience, training, or education; (2) the evidence is relevant; (3) the expert's opinion is based on information reasonably relied upon by experts in the particular field; (4) the expert testimony will assist the trier of fact to understand the evidence or to determine a fact in issue; and (5) the expert testimony will not create unfair prejudice or confuse or mislead the jury.<sup>18</sup>

The party seeking to introduce the expert testimony carries the burden of establishing its admissibility by a preponderance of the evidence.<sup>19</sup> A “‘strong preference exists’ for admitting expert opinions ‘when they will assist the trier of fact in understanding the relevant facts or the evidence.’”<sup>20</sup>

#### IV. DISCUSSION

Allergan's first basis to exclude Dr. Kaufman—that Dr. Kaufman misunderstands the nature of expert opinions—fails. After review of the relevant arguments and exhibits, the Court finds that Dr. Kaufman properly understands the role of expert testimony and rendering expert opinions.

Allergan's second basis—Dr. Kaufman is not qualified because he lacks the requisite knowledge, skill, experience, training, or education—fails. Dr. Kaufman is a practicing general surgeon, and he is opining on the significance of clinical trial data. Dr. Kaufman also advises

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<sup>14</sup> 526 U.S. 137 (1993).

<sup>15</sup> *Bowen*, 906 A.2d at 794 (citing *M.G. Bancorporation, Inc. v. LeBeau*, 737 A.2d 513, 522 (Del. 1999)).

<sup>16</sup> *Daubert*, 509 U.S. at 597.

<sup>17</sup> *Bowen*, 906 A.2d at 795.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Delaware ex rel. French v. Card Complaint, LLC*, 2018 WL 4151288, at \*2 (Del. Super. Ct. Aug. 29, 2018) (quoting *Norman v. All About Women, P.A.*, 193 A.3d 726, 730 (Del. 2018)).

hospitals on which medical devices, such as surgical mesh, to purchase.<sup>21</sup> Dr. Kaufman testified that he makes recommendations based on “finances” and “safety profiles” in his advisory role, and he acts more as a business advisor than a physician.<sup>22</sup> Dr. Kaufman is opining on, among other topics, the SURE studies and the reasonableness of Sofregen’s reliance on Allergan’s pre-closing representations regarding SERI. The cases Allergan cites as support are inapposite.<sup>23</sup> Dr. Kaufman is sufficiently qualified.

Allergan’s third basis—that several of Dr. Kaufman opinions should be excluded because they are not supported by sufficient facts or data—is unpersuasive. Allergan first argues Dr. Kaufman’s opinions regarding the reasonableness of Sofregen’s reliance on Allergan’s pre-closing representations are not based upon “any specific pre-closing representations.”<sup>24</sup> Allergan next argues Dr. Kaufman also lacks sufficient facts or data to opine about whether the SURE studies had a negative impact on the market for SERI.<sup>25</sup> Sofregen responds that Dr. Kaufman relied on his training and experience as a surgeon to evaluate SERI.<sup>26</sup> Sofregen maintains Dr. Kaufman also independently reviewed the SURE studies and the email exhibits in this case to form his opinions on the reliability of SERI and Allergan’s representations.<sup>27</sup>

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<sup>21</sup> See D.I. 186 at 5.

<sup>22</sup> *Id.*

<sup>23</sup> See *Goodridge v. Hyster Co.*, 845 A.2d 498, 503-04 (Del. 2004) (affirming a trial court ruling that granted a motion *in limine* to exclude an expert because the case was about a person injured by a forklift and the expert was not qualified to opine on proper forklift design safety because the expert had no experience in engineering or design safety, and because the expert never conducted any studies or even operated a forklift); *Specter v. Texas Turbine Conversions, Inc.*, 2020 WL 7234363, at \*4-5 (D. Alaska Dec. 8, 2020) (finding Dr. Kaufman in that case was not qualified to opine on the long-term effects of brain injuries or mental/emotional states because he is a general surgeon; but also finding Dr. Kaufman was “sufficiently qualified” to opine on the injured plaintiff’s injuries and cause of death). Here, Dr. Kaufman is opining on clinical data and representations Sofregen relied upon. The federal district court for the District of Alaska noted Dr. Kaufman was a surgeon “with over twenty years of training and employment in the medical field.” *Specter*, 2020 WL 7234363, at \*4.

<sup>24</sup> D.I. 181 at 6-7.

<sup>25</sup> *Id.* at 7.

<sup>26</sup> D.I. 186 at 8.

<sup>27</sup> *Id.* at 9.

Generally, “the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is for the opposing party to challenge the factual basis of the expert opinion on cross-examination.”<sup>28</sup> But when “the expert’s opinion is not based upon an understanding of the fundamental facts of the case, . . . it can provide no assistance to the [trier of fact] and such testimony must be excluded.”<sup>29</sup>

Allergan contends that Dr. Kaufman’s opinions are “not based upon an understanding of the fundamental facts” of this case. But that is not true. Dr. Kaufman reviewed the SURE studies, among other relevant scientific papers, and reviewed the communications between Sofregen and Allergan. If anything, this seems more like a challenge to the factual basis of Dr. Kaufman’s opinions, rather than Dr. Kaufman’s lack of understanding the fundamental facts. In such a situation, the Court will not exclude the expert. Instead, Allergan must draw those issues out on cross-examination.<sup>30</sup>

Allergan’s final basis—that Dr. Kaufman’s “non-expert opinions” should be excluded because they are inadmissible “common sense opinions”—is without merit. Allergan argues Dr. Kaufman opined about “matters concerning the FDA approval of SERI,” and that those opinions should be excluded because they are “common sense” and “empty[y].”<sup>31</sup> Sofregen counters that Dr. Kaufman did not opine on the FDA regulatory process, but rather on Sofregen’s expectations of obtaining FDA approval in light of the SURE-001 study before the negative SURE-002 and -006 studies were revealed.<sup>32</sup> Sofregen frames this as a “medical ethics” issue instead of a “regulatory process” issue.<sup>33</sup>

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<sup>28</sup> *Perry v. Berkley*, 996 A.2d 1262, 1271 (Del. 2010) (citing *Porter v. Turner*, 954 A.2d 308, 313 (Del. 2008)).

<sup>29</sup> *Id.*

<sup>30</sup> *See id.*

<sup>31</sup> D.I. 181 at 10.

<sup>32</sup> D.I. 186 at 10.

<sup>33</sup> *Id.*

D.R.E. 702 states in relevant part that an expert witness may testify “if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue.”<sup>34</sup> This is sometimes called the “relevancy requirement.”<sup>35</sup> Part of this inquiry includes the “distinction between testimony which is ‘common sense,’ and that which provides additional understanding of the issues of fact confronting the jury.”<sup>36</sup> Delaware courts hold that if the jury is “equally competent to form an opinion about the ultimate fact issues or the expert’s testimony is within the common knowledge of the jury,” then the trial court should exclude the expert’s testimony.<sup>37</sup>

The opinions that Dr. Kaufman sets forth are not “common sense.” Dr. Kaufman opines on, *inter alia*, the reasonableness of Sofregen’s expectations of getting FDA approval for SERI based on the results of the SURE-001 study. Dr. Kaufman further opines on the effect of the revelation of the SURE-002 and -006 studies and how those studies could affect gaining FDA approval for SERI. This is not like *Knott v. Covert*, where an expert’s opinion was excluded as “common sense” where the expert intended to opine on “the position of a scuff mark” on a vehicle in an auto accident case.<sup>38</sup> The case on which *Knott* relies, *Spencer v. Wal-Mart Stores East, LP*, is also distinguishable. There, the trial court excluded an expert who intended to opine on the safety code for clearing parking lots with respect to whether Wal-Mart was negligent in failing to clear its lot after a snowstorm.<sup>39</sup> The trial court did not permit the expert to testify

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<sup>34</sup> D.R.E. 702.

<sup>35</sup> See, e.g., *Knott v. Covert*, 2015 WL 196730, at \*2 (Del. Super. Jan. 15, 2015) (citing *In re Asbestos Litig.*, 911 A.2d 1176, 1199 (Del. Super. 2006)).

<sup>36</sup> *Id.* (quoting *Spencer v. Wal-Mart Stores East, LP*, 930 A.2d 881, 889-90 (Del. 2007)).

<sup>37</sup> *Id.* (citing *Spencer*, 930 A.2d at 890).

<sup>38</sup> See *id.* at \*3.

<sup>39</sup> See *Spencer*, 930 A.2d at 889-90.

because the issue was “common sense” when viewing the applicable safety code in light of the facts.<sup>40</sup> The Supreme Court affirmed.<sup>41</sup> The situation in our case is much different.

## V. CONCLUSION

The Court will “consider [Dr. Kaufman’s] testimon[ies] in connection with the purposes for which it [will be] offered and in light of any flaws in the testimony that may [be] exposed through cross-examination.”<sup>42</sup> Therefore, Allergan’s motion to exclude Dr. Kaufman is **DENIED.**

**IT IS SO ORDERED.**

May 25, 2023  
Wilmington, Delaware

/s/ Eric M. Davis  
Eric M. Davis, Judge

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<sup>40</sup> *See id.*

<sup>41</sup> *See id.* at 990.

<sup>42</sup> *See Beard Rsch., Inc. v. Kates*, 8 A.3d 573, 593 (Del. Ch. 2010); *see also id.* at 593 n.122 (citing *Trs. Of Chi. Painters & Decorators Pension, Health & Welfare, & Deferred Sav. Plan Trust Funds v. Royal Int’l Drywall & Decorating, Inc.*, 493 F.3d 782, 788 (7th Cir. 2007) (noting that there is less of a basis to use *Daubert* to exclude testimony entirely in a bench trial because the judge can consider any shortcomings in the expert’s testimony that are drawn out through cross-examination)).